

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

DECLARATION UNDER 37 C.F.R. §1.131

Applicants submit with this reply a declaration under 37 C.F.R. §1.131 in which they establish facts showing that the invention disclosed in the instant application was completed in the United States before 17 November, 1994, the filing date of the application that issued as U.S. Patent No. 5,693,609.

REMARKS

New Claims

Applicants cancel Claims 1-12; and submit new Claims 27-55. The new claims do not add new matter, and are supported by the specification, as filed. Correspondence between canceled Claims 1-24 and new Claims 27-55, and support for new Claims 27-28, 42-43, and 47 are indicated below.

New Claim	Support for New Claims
27	Canceled Claim 1; page 5, lines 8-12; and page 7, lines 27-29
28	Canceled Claim 1; page 5, lines 8-12; page 7, lines 23-26; and page 9, lines 5-13
29	Canceled Claim 1
30	Canceled Claim 1
31	Canceled Claim 2
32	Canceled Claim 3
33	Canceled Claim 4
34	Canceled Claim 5
35	Canceled Claim 6
36	Canceled Claim 7
37	Canceled Claim 8
38	Canceled Claim 9
39	Canceled Claim 11
40	Canceled Claim 10
41	Canceled Claim 12
42	Canceled Claim 13; page 5, lines 8-12; and page 7, lines 27-29
43	Canceled Claim 13; page 5, lines 8-12; page 7, lines 23-26; and page 9, lines 5-13
44	Canceled Claim 13
45	Canceled Claim 13
46	Canceled Claim 14

47	Page 4, line 7
48	Canceled Claim 17
49	Canceled Claim 18
50	Canceled Claim 19
51	Canceled Claim 20
52	Canceled Claim 21
53	Canceled Claim 22
54	Canceled Claim 23
55	Canceled Claim 24

New Claims 42-55 relate to the same subject matter as previously-canceled Claims 13-24. Applicants had previously canceled Claims 13-24 in an amendment dated June 18, 1997 in view of co-pending application 08/342,931, which subsequently issued as U.S. Patent No. 5,693,609. Applicants offer to submit a terminal disclaimer under 37 C.F.R. §1.321 should an obviousness-type double-patenting rejection be given. The offer to submit a terminal disclaimer over U.S. 5,693,609 is made to expedite prosecution of the present application, and is not an admission that the present invention is obvious with respect to U.S. 5,693,609.

Objection

On the PTO Form 326 that accompanied the Office Action, the Examiner indicated that Claims 4-8 were objected to. Applicants presume that the basis of the objection is the typographical error "humin" in Claim 3, from which Claims 4-8 depend. Applicants cancel Claim 3, and submit corresponding new Claim 32, wherein the word "human" is used. New Claims 33-37 correspond to canceled Claims 4-8, and depend from new Claim 32. Applicants respectfully request the Examiner to remove this objection, and not to object on the same grounds to new Claims 33-37.

Rejection of Claims 2, 5-6, and 25-26 under 35 U.S.C. §112, second paragraph

The Examiner rejected Claims 2, 5-6, and 25-26 under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

Applicants cancel Claims 2, 5, and 6, and submit corresponding new Claims 31, 34, and 35. New Claim 31 has a terminal period, as the Examiner required for canceled Claim 2, and new Claim 34 has the words "per milliliter" inserted, as the Examiner suggested for canceled Claim 5. In Claim 25, Applicants replace "fortified with" with the conjunctive "and." Applicants assert that, with these amendments, Claims 25-26, 31, and 34-35 are definite and comply with 35 U.S.C. §112, second paragraph. Applicants, therefore, respectfully request the Examiner to remove this ground of rejection.

Rejection of Claims 1-2 under 35 U.S.C. §102(e)

The Examiner rejected Claims 1 and 2 as allegedly anticipated under 35 U.S.C. §102(e) by Baker, et al. (U.S. Patent No. 5,693,609). Applicants respectfully traverse this rejection as it may apply to new Claims 27-31, which correspond to canceled Claims 1 and 2.

The invention claimed in Claims 27-31 requires fatty acid-acylated insulin, which is narrowly defined in the instant specification as human, beef, or pork insulin, that is, naturally-occurring insulins.¹

The reference under 35 U.S.C. 102(e) discloses fatty acid-acylated derivatives of certain insulin analogs. The term "insulin analog" was carefully defined in the reference to exclude naturally-occurring insulins.² Therefore, U.S. Patent No. 5,693,609 cannot anticipate the invention claimed in new Claims 27-31, because it does not describe the invention, as required by 35 U.S.C. §102(e).

Applicants, nevertheless, submit a declaration under 37 C.F.R. §1.131 to swear behind U.S. Patent No. 5,693,609 to eliminate U.S. Patent No. 5,693,609 as a potential reference under 37 C.F.R. §103(a). The submission of the declaration is

¹ The instant specification, page 3, lines 4-5.

not an admission that the invention in Claims 27-31 of the present application is obvious in light of U.S. Patent No. 5,693,609. On the contrary, Applicants assert that the invention claimed in Claims 27-31 is not obvious in light of U.S. Patent No. 5,693,609.

In view of the remarks above, Applicants respectfully request the Examiner not to reject new Claims 27-31 under 35 U.S.C. §102(e), or under 35 U.S.C. §103(a), because of U.S. Patent No. 5,693,609.

Rejection of Claims 3 and 9-12 under 35 U.S.C. §103(a)

Rejection of Claims 25-26 under 35 U.S.C. §103(a)

The Examiner rejected Claims 3, 9-12, and 25-26 under 35 U.S.C. §103(a) as allegedly unpatentable over Baker, et al. (U.S. Patent No. 5,693,609).

As mentioned above, Applicants herewith submit a declaration under 37 C.F.R. §1.131 to swear behind U.S. Patent No. 5,693,609 to eliminate U.S. Patent No. 5,693,609 as a potential reference under 37 C.F.R. §103(a). The submission of the declaration is not an admission that the invention in Claims 25-26, 32, and 38-41 of the present application is obvious in light of U.S. Patent No. 5,693,609.

Applicants respectfully request the Examiner to remove the rejection of Claims 25-26 under 35 U.S.C. §103(a), and to not reject new Claims 32, and 38-41 over U.S. Patent No. 5,683,609.

Havelund, US 5,750,497

In compliance with 37 C.F.R. §1.56, Applicants submit for the Examiner's consideration a number of publications that have come to their attention. In particular, Applicants point out that the application of

Serial No. 08/484,542

Havelund, et al. issued as U.S. Patent No. 5,750,497 on May 12, 1998.

Applicants respectfully remind the Examiner that the publication of Havelund's corresponding PCT application (WO95/07391) was the subject of the Office Interview with Mr. Steven P. Caltrider and Mr. James J. Kelley on December 17, 1997. The PCT publication was cited in the present application on a Form 1449.

In Applicants' view, there is conflict between the claims of U.S. 5,750,497 and Claims 25-55 of the present application.

Summary

Applicants cancel Claims 1-12, and submit new Claims 27-55. New Claims 27-55 are supported by the specification as filed, and add no new matter. Applicants respectfully assert that new Claims 27-41 remedy the objection that the Examiner raised, and are definite and patentable over U.S. Patent No. 5,693,609 that the Examiner cited in rejecting the present application. Applicants submit a declaration under 37 C.F.R. §1.131 to swear behind the application date of U.S. 5,693,609. Applicants also submit additional publications on a Form 1449, particularly Havelund, et al. (U.S. No. 5,750,497, issued May 12, 1998). Applicants respectfully request the Examiner to consider the newly-cited publications. Applicants respectfully assert that they have overcome the present grounds of rejection and objection, and are therefore entitled to have new Claims 27-55, and Claims 25-26 passed to issuance in light of the patents and publications that have thus far formed the bases of rejection in this application.

Serial No. 08/484,542

Respectfully submitted,

James J. Kelley

James J. Kelley
Attorney for Applicants
Registration No. P-41,888
Phone: 317-277-8110

Eli Lilly and Company
Patent Division/JJK
Lilly Corporate Center
Indianapolis, Indiana 46285

19 August 1998